

## REMARKS

### Status of the Claims

Prior to entry of the present Amendment and Response, claims 1-26 were pending in this application. Claims 1, 15, and 26 are the independent claims under consideration.

Claims 1, 3, 7-9, 11-20, and 22-26 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by a published International Application No. PCT/CA99/00405 by Taylor *et al.* ("Taylor"). Also, claims 1, 4-5, 10, 15, and 21 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by a published International Application No. PCT/US00/11380 by Hart *et al.* ("Hart"). Further, claims 1-2 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,416,267 to Garren *et al.* ("Garren"). Finally, claims 1 and 6 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Taylor in view of U.S. Patent Application Publication No. US 2002/0173754 A1 by Whitmore III ("Whitmore").

After entry of the present Amendment and Response, claims 1, 3-15, and 17-32 will be pending. In view of the above amendments and following remarks, reconsideration and withdrawal of all grounds of rejections of these claims are respectfully requested.

### Amendments to the Claims

Applicants have amended independent claims 1, 15, and 26 and added new claims 27-32 to more particularly point out and distinctly claim the subject matter Applicants regard as their invention. No new matter has been introduced; support for the amendments being found throughout the specification, for example, in paragraphs 0023, as well as in now-canceled claims 2 and 16, as originally filed. Also, support for the newly added claims 27-32 can be found throughout the specification, for example, in paragraph 0022.

### Claim Rejections under 35 U.S.C. § 102(b)

In order for a claim to be anticipated under 35 U.S.C. §102(b), each and every limitation thereof must be found in a single reference. Applicants respectfully submit that each of Taylor, Hart, and Garren fails to meet this exacting standard as applied to Applicants' claims, as explained below.

Taylor

Claims 1, 3, 7-9, 11-20, and 22-26 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Taylor. Applicants respectfully traverse this rejection to the extent it is maintained over independent claims 1, 15, and 26, as amended, or claims 3, 7-9, 11-14, 17-20, and 22-25 dependent therefrom, and submit that Taylor does not anticipate Applicants' claims because Taylor does not teach or suggest each and every limitation thereof.

Specifically, Applicants respectfully submit that Taylor does not teach or suggest at least a fixation element that is "substantially buoyant relative to at least one body fluid," as required by Applicants' independent claims 1, 15, and 26 as amended, or claims 3, 7-9, 11-14, 17-20 and 22-25 that depend therefrom.

Taylor discloses a ureteral stent having a bead (10) connected to a conventional stent (20) by a tether (16) for the purpose of converting that stent into one that may be non-surgically removed using a magnet-tipper catheter. See Taylor, page 6, lines 2-7, page 7, line 2, and Fig. 7. Taylor's bead (10) is an elongated ferromagnetic member, and, preferably, made of stainless steel. See Taylor, page 6, lines 8-10 and 15-16. Taylor also discloses another ureteral stent having a collapsible basket component (110) connected to a conventional stent (130) by a tether (116) for the purpose of converting that stent into one that may be non-surgically removed using an instrument that readily grasps the basket. See Taylor, page 12, lines 7-11, and Fig. 11. Taylor specifies that the basket may be formed of any suitable resilient material. See Taylor, page 12, lines 14-15. The basket may also be made of metal or metal alloy, such as stainless steel or nitinol. See Taylor, page 12, line 18.

In contrast to Applicants' claims 1, 15, and 26, as amended, Taylor is silent with respect to the buoyancy of the ferromagnetic bead (10) or resilient basket (110). Concerning Figure 14 of Taylor (cited on page 2 of the Office Action), Applicants respectfully submit that neither Figure 14, nor the corresponding description of Fig. 14 on page 14, lines 6-10 and page 15 line 30 to page 16, line 3 in Taylor discloses that the basket (110) is buoyant in a body fluid. Rather, Figure 14 merely depicts the basket (110) suspended in the bladder from the stent (130) by the tether (111). Applicants respectfully submit that Figure 14 does not depict any fluid in the bladder, nor does the corresponding description discuss bladder contents or fluid.

Thus, at least because Taylor does not teach or suggest a fixation element that is substantially buoyant relative to at least one body fluid recited in independent claims 1, 15, and 26, as amended, Applicants submit that these claims are novel and non-obvious over Taylor.

Accordingly, for the reasons stated above, Applicants respectfully submit that Taylor fails to be a proper anticipatory reference and thus amended independent claims 1, 15, and 26 are patentable. Without acquiescing to the rejections of claims 3, 7-9, 11-14, 17-20, and 22-25, Applicants note that these claims depend directly or indirectly from the allowable base claims, and include all of the limitations thereof, and, thus, are also patentable. Reconsideration and withdrawal of the rejection of claims 1, 3, 7-9, 11-15, 17-20, and 22-26 under 35 U.S.C. § 102(b) are respectfully requested.

Hart

Claims 1, 4-5, 10, 15, and 21 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hart. Applicants respectfully traverse this rejection to the extent it is maintained over independent claims 1 and 15, as amended, or claims 4-5, 10, and 21 dependent therefrom, and submit that Hart does not anticipate Applicants' claims because Hart does not teach or suggest each and every limitation thereof.

Specifically, Hart does not teach or suggest at least a "retention module comprising a fixation element attached to the elongated body portion by a tether connector" as well as that the fixation element is "substantially buoyant relative to at least one body fluid," as required by Applicants' independent claims 1 and 15, as amended, or claims 4-5, 10, and 21 that depend therefrom.

Hart discloses an expandable stent constructed of a woven tubular structure of multiple strands of elements. See Hart, page 3, lines 7-8. A retention member can be integrally formed at one or both of the ends of the stent. See Hart, page 3, lines 10-11 and page 11, line 14-15. Hart also discloses that a tether can be attached or formed at the end of the stent for assisting in the placement or the removal of the stent. See Hart, page 11, lines 25-27.

In contrast to Applicants' claims 1 and 15, as amended, Hart's retention member does not include "a fixation element attached to the elongated body portion by a tether connector." To the

extent Hart discloses a tether for assisting in the placement or the removal of the stent, such tether, however, does not attach any fixation element to the stent. Moreover, Hart is silent with respect to buoyancy of any components of his stent.

Thus, at least because Hart does not teach or suggest a retention module having a fixation element recited in independent claims 1 and 15, as amended, Applicants submit that these claims are novel and non-obvious over Hart. Accordingly, for the reasons stated above, Applicants respectfully submit that Hart fails to be a proper anticipatory reference and thus amended independent claims 1 and 15 are patentable. Without acquiescing to the rejections of claims 4-5, 10, and 21, Applicants note that these claims depend directly or indirectly from the allowable base claims, and include all of the limitations thereof, and, thus, are also patentable. Reconsideration and withdrawal of the rejection of claims 1, 4-5, 10, 15, and 21 under 35 U.S.C. § 102(b) are respectfully requested.

Garren

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Garren. Applicants canceled claim 2 thereby rendering the rejection thereof moot. Applicants, however, respectfully traverse this rejection to the extent it is maintained over independent claim 1, as amended, and submit that Garren does not anticipate this claim because Garren does not teach or suggest each and every limitation thereof.

Specifically, Garren does not teach or suggest at least “a retention module disposed proximal to said proximal end of said elongated body portion, said retention module comprising a fixation element attached to the elongated body portion by a tether connector,” as required by Applicants’ independent claim 1, as amended.

Garren discloses a stomach insert for treating obesity in humans by reducing the stomach volume. Garren’s stomach insert includes an inflatable balloon (10) (see Garren, col. 2, lines 9-13 and Figure 1), a standard stomach tube (20) (see Garren, col. 3, lines 18-19), and an insufflation tube (22) (see Garren, col. 3, lines 25-30). The insufflation tube (22) is attached to the balloon (110) See Garren, col. 3, lines 25-30

In contrast to Applicants’ claim 1, as amended, and contrary to the statement on page 3 of the Office Action, Garren’s balloon is not attached to the insufflation tube by a tether connector.

Moreover, Garren's balloon is not attached at all to Garren's stomach tube. Thus, Applicants respectfully submit that Garren's disclosure does not teach a fixation element attached to any elongated body portion by a tether connector.

Thus, at least because Garren does not teach or suggest a retention module having a fixation element recited in independent claim 1, as amended, Applicants submit that this claim is novel and non-obvious over Garren. Accordingly, for the reasons stated above, Applicants respectfully submit that Garren fails to be a proper anticipatory reference and thus amended independent claim 1 is patentable. Reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) are respectfully requested.

*Claim Rejection under 35 U.S.C. § 103(a)*

Claims 1 and 6 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Taylor in view of Whitmore. Applicants respectfully traverse this rejection to the extent it is maintained over independent claim 1, as amended, or claim 6 dependent therefrom, for the reasons provided below.

As a preliminary matter, Applicants respectfully note that the Office Action failed to communicate to Applicants with clarity required by M.P.E.P. 2106(VII), any findings or reasons to support the rejection of claim 1 under 35 U.S.C. § 103(a). Nevertheless, to expedite prosecution of this application, Applicants hereby address this rejection and respectfully submit that Taylor and Whitmore fail to render Applicants' claim 1 (as well as claim 6) obvious because neither Taylor, nor Whitmore, alone or in combination, teach or suggest the medical device recited in independent claim 1, as amended, or claim 6 dependent therefrom.

It is well settled that establishing obviousness requires a showing that the prior art provides every limitation of a claim and the invention as a whole. See M.P.E.P. §§ 2142, 2143. As a result, a reference, or combination of references, that does not teach or fairly suggest the invention as a whole can not render that claim obvious. See, e.g., M.P.E.P. § 2141.02. Also, to modify or combine references, there must be some suggestion or motivation to do so in the reference itself or in the knowledge generally available to one of ordinary skill in the art that lies outside the disclosure of the patent application. See, e.g., M.P.E.P. §2142 (8th Ed., August

2001). Absent this motivation, a rejection under 35 U.S.C. § 103(a) is improper and should not be maintained.

As explained above, Taylor does not teach a fixation element recited in independent claim 1, as amended. Because Taylor is silent with respect to the buoyancy of the disclosed ferromagnetic bead or the resilient basket, Applicants submit that Taylor fails to provide a requisite motivation to a skilled artisan to modify the teachings of Taylor in order to arrive at the invention recited in claim 1, as amended.

Further, Applicants respectfully submit that Whitmore does not cure the deficiencies of Taylor. Whitmore discloses a stent having a reduced wall thickness at the proximal region for the purpose of making the stent more pliable, flexible, and supple to adapt or partially yield to the closing or narrowing of the ureter in the junction during constriction. See Whitmore, paragraph 0031. Whitmore, however, is also silent with respect to the buoyancy of the fixation element. Thus, Whitmore also fails to teach or suggest a fixation element recited in the Applicants' claims 1, as amended.

Accordingly, Taylor and Whitmore, either alone or in combination, fail to teach or suggest every limitation of Applicants' claim 1, and do not motivate a skilled artisan to modify their disclosures to arrive at the medical device recited in the independent claims 1. Accordingly, Applicants respectfully submit that independent claim 1, as amended, is allowable. Without acquiescing to the rejection of claim 6, Applicants note that this claim depends directly or indirectly from the allowable base claim, and, thus, also is allowable. In light of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

### **CONCLUSION**


Applicants respectfully submit that, in light of the foregoing remarks, claims 1, 3-15, and 17-32 are in condition for allowance and request the application proceed to issue. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,

Date: August 7, 2003

Tel. No.: (617) 248-7044  
Fax No.: (617) 248-7100

2657270

  
Ronda P. Moore, D.V.M.  
Reg. No. 44,244  
Attorney for the Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110